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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/512,926	02/25/2000	Fred S. Lamb	P-1057	6913

7590

06/13/2003

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EXAMINER

KIM, JENNIFER M

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 06/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/512,926

Applicant(s)

LAMB, FRED S.

Examiner

Jennifer Kim

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-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6-11, and 23 ¹⁴⁻²¹ is/are pending in the application.
- 4a) Of the above claim(s) 14-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6-11 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

The amendment filed on January 23, 2003 and April 10, 2003 have been received and entered into the application.

Any rejection of record not addressed herein is withdrawn.

Response to Arguments

Applicant's arguments filed January 23, 2003 have been fully considered but they are not persuasive.

Applicant argues essentially that claim 1 is directed to a method to normalize the contractile response of an endothelially-compromized vascular smooth muscle cell to a vasoconstrictor agonist in a patient in need of such normalization, comprising administering a effective amount of a CLC3 blocker, and Grainger et al. disclose that the therapeutic agent that can inhibit the activity of a vascular smooth muscle such as proliferation, contraction and migration, and there is nothing in Grainger et al. that teaches or suggests normalizing the contractile response of an endothelially-compromised vascular smooth muscle cell to at least one vasoconstrictor agonist. Applicant further argues that the "inhibition" of VSMC activity is not the equivalent of smooth muscle cell "normalization" and that even if tamoxifen has been reported to "inhibit" vascular smooth muscle cell contraction, there is nothing in the cited art to suggest that it can correct or normalize the effect of vasoconstrictor agonists on

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endothelially-compromised VSMC. This is not persuasive because as asserted by the Applicant that Grainger et al. disclose that the therapeutic agent (i.e. tamoxifen) can inhibit the activity of the vascular smooth muscle cell (VSMC) such as contraction. This disclosure of "inhibiting contraction" encompasses the "normalization" since the effect of inhibition the contraction of VSMC would "normalize" the VSMC.

In view of the above Office Action of January 29, 2003 is deemed proper and asserted with full force and effect herein to obviate applicant's claims.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 6-11 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grainger et al. (U.S. Patent No. 6,197,789 B1).

Grainger et al. teach Applicant's active agent was exemplified to illustrate the inhibition of the pathological activity of these smooth muscle cells, by inhibiting the activation including contraction. (abstract, column 3, lines 17-22, column 17, lines 41-47). Grainger et al. teach that Applicant's active agent is useful on vascular smooth muscle cells to inhibit the pathological activity of the smooth muscle cells, and to inhibit the activation of endothelial cells associated with vascular surgery, diabetes, hypertension, and coronary artery blockage. (abstract, column 4 lines 7-16, column 5,

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line 65 through column 6, line 30, column 7, lines 15-33, column 8, lines 11-20, column 10 lines 51-57, column 15, line 54, column 18, lines 34-44, column 24, lines 47-50, and column 25, lines 4-8). Grainger et al. teach the procedural vascular traumas including surgical procedures include vascular surgery (e.g. angioplasty, coronary bypass) and the pathologies (atherosclerosis, myocardial infarction and stroke) and be prevented by the administration of the active agent. (column 3, lines 30-51, column 4, lines 8-25).

Grainger et al. do not explicitly teach "normalize the contractile response" and further comprising the agents set forth in claim 11.

It would have been obvious to one of ordinary skill in the art to employ tamoxifen in normalizing the contractile response of vascular smooth muscle because Gringer et al. teach that tamoxifen inhibits contraction of vascular smooth muscle which would encompass the effect of normalization of the vascular smooth muscle. It is noted that by inhibiting contraction, it would normalize the vascular smooth muscle in its normal state. Further, to incorporate other agents similarly useful in treatment of diabetes, hypertension and coronary artery disease together with the active agents in Grainger et al. which is also taught by Grianger to be useful in treatment of diabetes and pathological condition related to coronary artery disease is obvious due to their common utility (see In re Kerkhoven, 205 USPQ 1069(CCPA 1980)). One of ordinary skill in the art would have been motivated to further combine other agents set forth in claim 11 to achieve at least an additive effect.

None of the claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

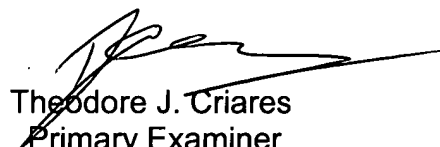
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 703-308-2232. The examiner can normally be reached on Monday through Friday 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned

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are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Theodore J. Criares
Primary Examiner
Art Unit 1617

jmk
June 11, 2003